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K010081

FEB - 5 2001

# Exactech® AcuMatch™ Integrated Hip System
# L-Series Unipolar Endoprosthesis

## 510(k) Summary of Safety and Effectiveness
## Special 510(k)

*Sponsor:* **Exactech® Inc.**
**2320 N.W. 66th Court**
**Gainesville, Florida 32653**

**Phone:** **(352) - 377 - 1140**
**Fax:** **(352) - 378 - 2617**

**FDA Establishment Number 1038671**

*Contact:* **Gary J. Miller, Ph.D.**
**Executive V.P. of Research and Development**

*Date:* 01|08|01

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# L-Series Unipolar Endoprosthesis

## 510(k) Summary of Safety and Effectiveness
## Special 510(k)

**Classifications / Proprietary Names:**

| | |
|---|---|
| Classification Name: | Prosthesis, Hip, Hemi-, Femoral, Metal |
| Product Code: | KWL |
| C.F.R. Section: | 888.3360 |
| Device Class: | II |
| Classification Panel: | Orthopedic |
| Classification Name: | Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented |
| Product Code: | KWY |
| C.F.R. Section: | 888.3390 |
| Device Class: | II |
| Classification Panel: | Orthopedic |
| Trade / Proprietary Model Names: | AcuMatch L-Series Unipolar Endoprosthesis |

**Legally Marketed Devices for Substantial Equivalence Comparison:**

The Exactech AcuMatch L-Series Endoprosthesis is made of similar materials and is of a similar design to other legally marketed femoral components, most notably the Exactech Opteon Endoprosthesis:

| Model | Manufacturer | 510(k) Number |
|---|---|---|
| Opteon Unipolar Endoprosthesis | Exactech, Inc. | K960538 |
| Unitrax Unipolar System | Howmedica | ---------- |
| Unipolar System | Smith & Nephew | ---------- |
| Bio-Moore II | BioMet | ---------- |

The proposed AcuMatch L-Series Unipolar Endoprosthesis has the same basic external design features as our predicate Exactech Opteon Endoprosthesis. These features include a material composition of cobalt chrome and identical off set sizing options. The main difference between the two designs is that the predicate Opteon model is a one-piece component and the L-Series model is a modular device with interchangeable neck segments.

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In addition, the proposed L-Series Unipolar Endoprosthesis provides features similar to models marketed by Smith & Nephew, Howmedica and Biomet.

All the components have a spherical design, are made of cobalt chrome and supplied sterile.

**Device Description:**

The AcuMatch L-Series Unipolar is a modular endoprosthesis consisting of a truncated spherical head and interchangeable neck sleeves. The device is fully machined from cobalt chrome conforming to ASTM F1537-94. The size offerings include 15 head sizes (38 mm – 62 mm) with four available offset options (-5, +0, +5 and +10).

Selection of the Acumatch Unipolar component is made by the surgeon in relationship to the requirements of the patient. The surgeon should become thoroughly familiar with the technique of implantation of the prosthesis by: 1) appropriate reading of the literature and 2) training in the operative skills and techniques required for hip arthroplasty surgeries.

**INTENDED USE**
The AcuMatch L-Series Unipolar Endoprosthesis was designed to address the more conservative clinical indications for joint replacement surgery. The L-Series Unipolar modular head is used in hemiarthroplasty of the hip. If total joint replacement is required at a future time, the procedure can be accomplished without removing the femoral stem.

**INDICATIONS**
The AcuMatch L-Series Unipolar Endoprosthesis is indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. It is also indicated for use in replacement of the femoral head following femoral neck fracture.

**CONTRAINDICATIONS**
The AcuMatch L-Series Unipolar Endoprosthesis is contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age, or activity level would cause the surgeon to expect early failure of the system. The L-Series Unipolar is also contraindicated for use in patients with evidence of degenerative changes in the acetabulum and/or pelvic fractures.

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*Packaging Information:*

| Material | Composition |
|---|---|
| Inner / Outer Trays | PETG – 0.040" thickness |
| Tray Lids | Spun-Bonded Olefin - Tyvek® |
| Inserts | Medium grade LD45 Foam |
| Box | Heavy weight cardboard |
| Outer Shrink-Wrap | Clear, Light-Weight Plastic |
| Shipping Cartons | Heavy-weight Corrugated Cardboard |

Utilization and implantation instructions are included in the package insert provided with each product. The name, size, dimension, material, lot, serial number and sterility status are indicated on the labeling.

*Sterilization Specifications:*

Method: Gamma radiation (Cobalt 60 source)
Dose: 25 – 37 kGy
Sterility Assurance Level (SAL): $10^{-6}$

**Performance Data Summary:**

Functional testing and engineering analysis were conducted to verify that the implant performance would be adequate for anticipated *in vivo* loading. Based on Finite Element Analysis (FEA), fatigue testing of production quality parts, and material certifications we conclude that the Exactech AcuMatch L-Series Unipolar Endoprosthesis is substantially equivalent to our predicate Exactech Opteon Unipolar device (#K960538).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2001

Ms. Lisa Simpson
Regulatory Representative
Exactech, Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K010081
Trade Name: Exactech® AcuMatch™ L-series Unipolar Endoprosthesis
Regulatory Class: II
Product Code: KWY
Dated: January 8, 2001
Received: January 10, 2001

Dear Ms. Simpson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Ms. Lisa Simpson

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhern

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Exactech® AcuMatch™ Integrated Hip System**
**L-Series Unipolar Endoprosthesis**

**Indications for Use**

**510(k) Number:** K010081

**Device Name:** Exactech® AcuMatch™ Integrated Hip System
L-Series Unipolar Endoprosthesis

**INDICATIONS**
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Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K010081

Prescription Use Yes or Over the Counter Use No